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May 17, 1999

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VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments to Advance Notice of Proposed Rulemaking on Irradiation in the Production, Processing, and Handling of Food: Docket No. 98N-1038

Dear Sir:

We enclose, on behalf of Enzyme Bio-Systems Ltd. ("EB"), comments concerning the above-referenced Advance Notice of Proposed Rulemaking. 64 Fed. Reg. 7834 (Feb. 17, 1999). As directed by the Federal Register notice, two copies are being submitted.

Please let us know if you have any questions about this submission.

Very truly yours,

Gary L. Yingling

Suzan Onel

McKenna & Cuneo
Counsel for Enzyme Bio-Systems Ltd.

GLY/so
Enclosure
cc: Enzyme Bio-Systems

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98N 1038

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Re: Comments to Advance Notice of Proposed Rulemaking on Irradiation in the Production, Processing, and Handling of Food: Docket No. 98N-1038

Dear Sir or Madam:

On behalf of Enzyme Bio-Systems Ltd. ("EB"), we are submitting comments concerning the Food and Drug Administration's ("FDA") Advance Notice of Proposed Rulemaking ("ANPR") for Irradiation in the Production, Processing, and Handling of Food, which was published in the Federal Register on February 17, 1999. 64 Fed. Reg. 7834 (1999). EB is a manufacturer of enzymes for food and industrial purposes. These comments are limited to the request for comments on the following question:

Question 6: ***With respect to foods containing irradiated ingredients, are consumers misled by the absence of a radiation disclosure statement? Would consumers be misled by the presence of such a statement?***

To summarize, EB does not believe consumers are misled by the absence of a radiation disclosure statement on foods containing irradiated ingredients. EB supports a policy that the labeling requirements for irradiated ingredients in multiple-ingredient food be the same as for any other processed ingredients, namely, that they be declared by their common or usual name without any requirement for stating whether or how the ingredient was processed.

A. Action Requested

EB respectfully requests that FDA keep a policy that irradiated ingredients used in multiple-ingredient food products be regulated the same as other processed ingredients and not be required to bear special labeling stating whether or how they were processed.

B. Discussion

As FDA has acknowledged in numerous Federal Register notices, irradiation of an ingredient in a multiple-ingredient food ("second generation food") that itself has not been irradiated represents a situation where special labeling is unnecessary; irradiation is a processing step and consumers recognize that multiple-ingredient food products have been processed without the need for special labeling to disclose that they have been processed. EB agrees with these reasons and further offers that the above policy is consistent with FDA's exemption of processing aids from the food labeling requirements under 21 C.F.R. § 101.100(a)(3)(ii). Therefore, EB does not believe consumers are misled by the absence of a radiation disclosure statement and, in fact, consumers may be misled by the presence of one.

1. Irradiation is a Processing Step

EB agrees that FDA's current policy of regulating irradiation as a process and not an ingredient is correct. Although regulated for food use under the food additive provisions, FDA has stated that, "with respect to ingredient labeling, food irradiation need not be regulated the same as food additives that are used as ingredients in food, and therefore, need not be identified on the label as an 'ingredient.'" Proposed Rule: Irradiation in the Production, Processing, and Handling of Food, 49 Fed. Reg. 5714, 5718 (Feb. 14, 1984).

Consistent with this approach, the ionizing radiation regulation for the treatment of food exempts from the labeling disclosure requirement a finished food product "that merely contains an irradiated ingredient but that has not itself been irradiated." 21 C.F.R. § 179.26(c)(2).

2. Consumers are Not Misled by the Absence of a Disclosure Statement

EB agrees with FDA's past statements that multiple-ingredient food products that contain single ingredients that have been irradiated do not require special labeling to disclose whether or how an ingredient was processed. As discussed in detail in FDA's 1986 final rule on irradiation in the production, processing, and handling of food and its 1988 response to objections, FDA historically has tied its disclosure requirement for processing agents or methods to those that are material (e.g., have an effect on the characteristics of a food) and necessary to prevent consumer deception as to whether the product has been processed. Because multiple-ingredient foods are obviously processed, the processing step is not a "material fact" requiring disclosure and is adequately covered under the general processing aid regulation. 21 C.F.R. § 101.100(a)(3)(ii).

(a) Multiple-Ingredient Food Products are Obviously Processed

In its final rule authorizing irradiation in the treatment of food, FDA stated in its preamble that the retail label requirements for irradiated food were based upon misbranding considerations and not on food safety or health risk. See Final Rule: Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg.13376, 13389 (Apr. 18, 1986). While there is an argument that even first generation labeling is misleading and confusing to the purchaser and/or consumer because irradiation is a processing step no different from any other, FDA clearly acknowledged that the irradiation of one ingredient in a multiple-ingredient food (i.e., a "second generation food") is unnecessary "because such a food has obviously been processed." Id. EB agrees with this conclusion.

Because consumers do not expect a multiple-ingredient food to look, smell, or taste the same as a fresh or unprocessed food, or have the same shelf-life, they do not need special labeling to recognize that a food has been processed. Therefore, EB agrees with FDA's decision not to require a radiation disclosure statement on "food that contains an irradiated ingredient (second generation food) but that has not itself been irradiated." Id. EB believes this policy is sound and supported in law and fact.

(b) Processing Aids are Exempt from the General Food Labeling Requirements of FDC Act § 403(i)(2)

FDA also has concluded that the labeling requirements for irradiated ingredients in a multiple-ingredient food should be the same as for any other processed ingredient. Again, EB agrees with this conclusion.

The Federal Food, Drug, and Cosmetic ("FDC") Act requires that the label of a food fabricated from two or more ingredients bear the common or usual name of each ingredient (except for spices, flavorings, and colorings); however, it does not require that the label declare details of processing for each ingredient. FDC Act § 403(i)(2). Consistent with this regulation, FDA implemented 21 C.F.R. § 101.100, which states that processing aids are exempt from the food labeling requirements of FDC Act § 403(i)(2) if certain criteria are met. Specifically, substances that are added to a food for their technical or functional effect in the processing, but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food are not required to be listed on the label of a food product. 21 C.F.R. § 101.100(a)(3)(ii)(c). To illustrate, a combination rice/noodle product that contains an ingredient that has been treated with ethylene oxide to control pathogens is not required to list ethylene oxide on its label if it meets the above definition of a processing aid.

While EB agrees that there may be some circumstances where FDA may need to deviate from this general rule, such situations must be supported by some evidence of necessity from a misbranding, food safety, or health risk perspective. See FDC Act § 201(n). As FDA stated in its 1988 response to objections, "FDA had no evidence that irradiation of an ingredient would affect the characteristics of a multiple-ingredient food in any significant way." 53 Fed. Reg. 53176, 53205 (Dec. 30, 1988). EB submits that no information exists now that would suggest that this conclusion would be any different today and would further suggest that labeling the first generation food is similarly unnecessary in view of the description of irradiation as a processing aid. Therefore, EB supports the agency's conclusion that "the labeling requirements for irradiated ingredients should be the same as for any other processed ingredients, namely, to declare them by their common or usual name without any requirement for stating whether they were processed." Id.

To again use our rice product illustration, consistent with 21 C.F.R. § 101.100(a)(3)(ii)(c), the labeling of a rice/noodle product containing an ingredient

that has been treated with irradiation as a processing step to control pathogens should be no different than if it were treated with ethylene oxide.

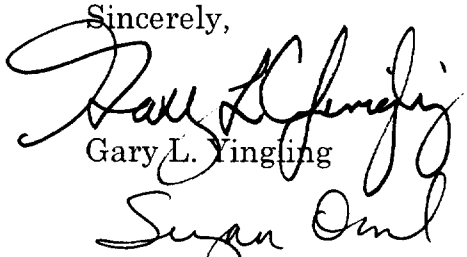
Finally, EB is concerned that if an irradiation disclosure statement is required, it could mislead consumers because other products which do not contain such labeling, but are treated by alternative forms of processing (e.g., ethylene oxide), would not be labeled as to the processing. This, in and of itself, would be counter to the intent of the FDC Act and its implementing regulations.

C. Conclusion

EB appreciates the opportunity to provide these comments regarding the agency's irradiation ANPR. As discussed above, EB believes that FDA's current policy with respect to the labeling of irradiated ingredients used in multiple-ingredient foods is consistent with the FDC Act, the agency's implementing regulations, and the public policy goal of providing clear, non-misleading information to consumers. As such, EB supports FDA's existing policy.

If you have any questions on the foregoing, please feel free to contact us.

Sincerely,



Gary L. Yingling

Suzan Onel

McKenna & Cuneo
Counsel for Enzyme Bio-Systems Ltd.

GLY/so
cc: Enzyme Bio-Systems

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